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No. 06-1249

IN THE
Supreme Court of the United States

WYETH,
Petitioner,

v.

DIANA LEVINE,
Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF FOR CONSUMERS UNION OF UNITED STATES, INC., AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether Congress intended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., setting forth duties between drug manufacturers and regulator, to pre-empt drug manufacturers' independent duty of care and duty to warn consumers under state law.

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INTEREST OF AMICUS CURIAE[1]

Consumers Union of United States, Inc., publisher of *Consumer Reports*, is a nonprofit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health and personal finance. Consumers Union's publications have a combined paid circulation of approximately 8.5 million. These publications regularly carry articles on Consumers Union's own product testing; on health, product safety, and marketplace economics; and on legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and services, and noncommercial contributions, grants, and fees. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

Consumers Union's mission is "to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves." In line with that mission and our assessment of priorities,

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[1] Pursuant to Rule 37.3(a) of the Rules of the Supreme Court of the United States, petitioner and respondent have lodged letters with the Court consenting generally to the filing of briefs *amicus curiae*, and accordingly, petitioner and respondent have consented to the filing of this brief. No counsel for a party in *Wyeth v. Levine*, Case No. 06-1249, authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* Consumers Union, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief. See Sup. Ct. R. 37.6.

Consumers Union has actively worked for a fair and just marketplace for consumers in critical areas implicated by this case, including prescription drugs, drug advertising, health care, and patient safety. Consumers Union has filed actions in both state and federal courts in order to protect consumers, and has actively participated in a variety of proceedings before both state and federal regulatory agencies. For example, Consumers Union played an active role in securing the passage of the Federal Food, Drug, and Cosmetic Act of 1938 and the 1962 amendments to the Act. It has been extremely active in the area of testing, evaluating, and rating of prescription drugs and health services, in order to inform consumers and to advocate for consumers before Congress, state legislatures, and regulatory agencies. Consumers Union filed amicus briefs on pre-emption in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and in *Riegel v. Medtronic, Inc.*, 552 U.S. ___, 128 S. Ct. 999 (2008).

SUMMARY OF ARGUMENT

Petitioner Wyeth manufactured and sold Phenergan, a drug for the treatment of nausea. The drug manufacturer filed an application under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b), to sell the new drug in interstate commerce. After pre-market review, the Food and Drug Administration approved the application in 1955. Jt. App., at 266-267; see also Pet. Br., at 11. The agency concluded that Wyeth's new drug met the minimum standards of safety for introduction into interstate

commerce. 21 U.S.C. § 355(a).[2] Neither the Act nor the Food and Drug Administration's specific review and approval purported to repeal or pre-empt Wyeth's independent duties to its consumers under state tort law, namely its duty of care and its duty to warn.

In post-market experience, Phenergan has caused gangrene, resulting in amputation, when administered by certain intravenous injection. The pre-market tests, application, review and approval did not disclose this grave danger, but it became apparent after post-market sales to consumers. See, e.g., Jt. App., at 268-269 (report of adverse reaction in 1965); *id.*, at 237, 240 (decision on motion for judgment, finding knowledge of danger "[s]ince at least 1976 ").

After an intravenous injection of Phenergan in 2000, Diane Levine, a guitarist and pianist, developed gangrene in her right hand, requiring amputation of her right arm at the elbow. Jt. App., at 237-238. Levine filed suit to recover damages for her loss. Her complaint invoked the basic duty of care and duty to warn between drug manufacturer and consumer, not the regulatory duties between drug manufacturer and Food and Drug Administration. She alleged that the drug information failed to instruct the clinician to dilute the drug and to administer the drug through a "running IV"; that the information failed to provide

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[2] In 1955, section 355 required pre-market review and approval to assess general safety. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052. In 1962, Congress added the requirement to assess general effectiveness. Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

adequate warnings that intra-arterial injection or extravasation could cause irreversible gangrene and loss of limb; and that Phenergan was not reasonably safe due to inadequate warnings and instructions regarding foreseeable risks of harm. Complaint ¶¶ 5-6, Jt. App. 14, 14-15. She alleged that the drug manufacturer had known that its warnings were inadequate and unsafe in this regard since 1987. *Id.*, ¶¶ 10-16, Jt. App., at 15-17. She concluded that Wyeth's "conduct . . . was negligent" and this "negligence and/or gross negligence was the proximate cause of plaintiff's injuries," and she prayed for "appropriate damages for her loss." *Id.*, ¶¶ 19-20, Jt. App., at 17.

Wyeth claims pre-emption because the drug and labeling received pre-market review and approval from the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 355.

Neither the Act in general nor the provisions on pre-market review of new drugs in particular include any term expressly pre-empting state tort remedies. As the Court observed in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Act regulates "the relationship between a federal agency and the entity it regulates." 531 U.S., at 347 (discussing parallel provisions on pre-market review of medical devices under the Federal Food, Drug, and Cosmetic Act). It does not purport to regulate the distinct relationship between the manufacturer and the consumer. See also *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94-95 (2d Cir. 2006) (distinguishing

claims "premised on traditional duties between a product manufacturer and . . . consumers" and claims premised on a "duty between a manufacturer and a federal agency"), *aff'd by equally divided Court sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. ___, 128 S. Ct. 1168 (2008) (per curiam). Instead, that separate relationship has long been governed by the duty of care and duty to warn under state common law, tort, and products liability. See Section I, *post*, at 6.

The legislative history of the Act, and the concurrent history of cases recognizing and enforcing drug manufacturers' duties to consumers under state law, confirm the fundamental presumption against pre-emption. See Section II, *post*, at 9. This does not surprise. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." E.g., *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). As a significant majority of courts have held, the Federal Food, Drug, and Cosmetic Act sets minimum standards for introduction into interstate commerce, and state laws requiring additional warnings to state consumers do not conflict with the Act. See Section III, *post*, at 19.

ARGUMENT

I. DRUG MANUFACTURERS' PRE-MARKET DUTIES TO THE FOOD AND DRUG ADMINISTRATION ARE SEPARATE AND DISTINCT FROM THEIR POST-MARKET DUTY OF CARE AND DUTY TO WARN THEIR INDIVIDUAL CONSUMERS.

Under the Federal Food, Drug, and Cosmetic Act, drug manufacturers must file an application and receive approval before introducing any new drug into interstate commerce. 21 U.S.C. § 355(a).

The application shall include the drug's composition, how it is manufactured and packaged, the proposed labeling, reports of investigations showing whether the drug is safe for use and effective in use, and samples of the drug if required. *Id.*, § 355(b)(1). Within 180 days, the agency shall either approve the application, or notify the applicant that it may elect a hearing. *Id.*, § 355(c)(1). The agency shall approve the application, unless one of seven enumerated grounds exists. *Id.*, § 355(d). The agency shall not approve the application if the reported investigations were not adequate to show, or there is insufficient information to determine, whether the drug is safe; or the manufacturing and packaging are inadequate; or the agency lacks substantial evidence that the drug will have the effect claimed; or certain patent information is missing; or the proposed labeling is false or misleading in any particular. *Ibid.* The agency may subsequently withdraw approval to engage in interstate commerce under enumerated circumstances. *Id.*, § 355(e). These are disclosures to and duties

between regulator and regulated entity, to obtain approval for introduction of the new drug into interstate commerce.

Between drug manufacturer and consumer, however, the drug manufacturer's duties are quite different. The trial court below explained those duties between drug manufacturer and consumer under Vermont law in its instructions to the jury:

> Duty of Care
>
> The manufacturer of a product such as Wyeth has a duty to take reasonable steps to notify users of the product--in this case the medical community--of the risks and dangers of the product and to provide adequate instructions about how to use the product safely. This standard of conduct does not require that useful drugs with dangerous potential be removed from the market. Instead, the law requires that Wyeth exercise reasonable care to warn or protect against the risks.
>
> . . . Warnings for prescription drugs are intended for the physician and his staff whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects.

Duty to Warn

> . . . The manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or in the exercise of reasonable care, should have known to exist.
> . . .
>
> . . . .
>
> Strict Liability--Failure to Warn
>
> A manufacturer of a product such as Phenergan is responsible for harm to a person caused by a defective product that reaches a user without undergoing substantial change.

Jt. App., at 227, 227-231.

The jury may consider evidence that the drug manufacturer complied with the Food and Drug Administration's requirements, but that evidence does not prove that the drug manufacturer's warnings met its duties to the consumer. *Id.*, at 227-228.

In short, the drug manufacturers' pre-market duties to the Food and Drug Administration in order to secure prior approval for interstate commerce, are separate and distinct from its subsequent, post-market duties to actual consumers under state law. The Federal Food, Drug, and Cosmetic Act does not pre-empt or conflict with these independent duties drug manufacturers have under state law.

II. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT REGULATES DUTIES BETWEEN DRUG MANUFACTURER AND REGULATOR, AND DOES NOT PRE-EMPT DRUG MANUFACTURERS' INDEPENDENT DUTIES TO CONSUMERS UNDER LONG-ESTABLISHED STATE POLICE POWERS.

The Supreme Court of Vermont agreed with the preponderance of courts that the Federal Food, Drug, and Cosmetic Act does not pre-empt state failure-to-warn claims. App. to Pet. for Cert. 15a; see, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. ___, ___ & n. 11, ___ & n. 16, 128 S. Ct. 999, 1017 & n. 11, 1018-1019 & n. 16 (2008) (Ginsburg, J., dissenting) (collecting cases).

In analyzing whether the Federal Food, Drug, and Cosmetic Act pre-empts a drug manufacturer's duty of care and duty to warn consumers under state laws, Congressional intent is the touchstone. E.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987) (in deciding whether federal law pre-empts state law, "our sole task is to ascertain the intent of Congress"); *Rice*, 331 U.S., at 230 ("the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (same).

The statute itself is the first indicia of intent. When Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938, it included no provision to pre-

empt state law. *Jones v. Rath Packing Co.*, 430 U.S. 519, 538 (1977) ("The FDCA contains no pre-emptive language."); see also *Riegel*, 552 U.S., at ___, 128 S. Ct., at 1016 (Ginsburg, J., dissenting).

Where a statute–such as the Federal Food, Drug, and Cosmetic Act–expresses no intent or purpose to pre-empt state laws, the Court presumes that Congress did not intend to pre-empt states laws. E.g., *Lohr*, 518 U.S., at 485 ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."); *Hillsborough County*, 471 U.S., at 715 ("presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause"); *Rice*, 331 U.S., at 230 ("the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."). A long history of state tort remedies–as here–against manufacturers in the area at issue "adds force to the basic presumption against pre-emption." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 449 (2005); cf. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251-256 (1984) (Congress assumed that existing state tort remedies would be available). Wyeth faces a "heavy burden of persuasion" to demonstrate the requisite "clear and manifest purpose of Congress" that alone can overcome that presumption. *Johnson v. Fankell*, 520 U.S. 911, 917 (1997); *Rice*, 331 U.S., at 230.

The legislative history of the Act, and the concurrent history of cases recognizing and enforcing

drug manufacturers' independent duties to consumers under state law, confirm this fundamental presumption against pre-emption.

A. Federal Food and Drugs Act of 1906

The basic structure of the Food, Drug, and Cosmetic Act and the argument against pre-emption date back over 100 years, to the Federal Food and Drugs Act of 1906, Pub. L. 59-384, ch. 3915, 34 Stat. 768, the predecessor to the Food, Drug, and Cosmetic Act of 1938.

The Federal Food and Drugs Act of 1906 prohibited manufacture of and interstate commerce in adulterated or misbranded foods and drugs, as defined in the act. *Id.*, §§ 1-2, 7-8, 34 Stat. at 768, 769-770 (repealed by Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 902(a), 52 Stat. 1040, 1059). The act did not purport to pre-empt the manufacturer's duty of care and duty to warn its consumers, nor the traditional state laws enforcing those duties. For example, a state law in Wisconsin generally prohibited selling food that contains the preservative benzoate of soda. A federal regulation under the Federal Food and Drugs Act of 1906 provided that addition of the preservative benzoate of soda was not injurious to health and was not objectionable under the federal act. When a food shipper argued that the federal regulation pre-empted the state law, even as applied to local retail sales, this Court disagreed:

> When objects of commerce get within the sphere of state legislation the State may exercise its independent judgment and prohibit what Congress did not see fit to forbid. . . . The Food and Drugs Act does not interfere with state regulation of selling at retail. [Citations omitted.] Such regulation is not an attempt to supplement the action of Congress in interstate commerce but the exercise of an authority outside of that commerce that always has remained in the states.

Weigle v. Curtice Brothers Co., 248 U.S. 285, 288 (1919); see also *Savage v. Jones*, 225 U.S. 501, 539 (1912) (Federal Food and Drugs Act of 1906 does not pre-empt state statute requiring disclosure of additional matters, *viz.* the product's ingredients, in order to protect against deception and ensure that purchasers are informed about what they are buying by certificate and label requirements).

Accordingly, state-based tort claims proceeded without pre-emption under the predecessor Federal Food and Drugs Act of 1906. See, e.g., *Mazetti v. Armour & Co.*, 75 Wash. 622 (Wash. 1913); *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154 (Minn. 1918); *Kelly v. John R. Daily Co.*, 56 Mont. 63 (Mont. 1919); *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925); *Portage Markets Co. v. George*, 111 Ohio St. 775 (Ohio 1924); *Machlitt v. Myers*, 23 Ohio App. 160 (Ohio App. 1926); *Coca Cola Bottling Works v. Selvidge*, 4 Tenn. App. 558 (Tenn. Ct. App. 1927); *Ritchie v. Sheffield Farms Co.*, 222 N.Y.S. 724 (N.Y.

Mun. Ct. 1927); *Abbott Laboratories v. Lapp*, 78 F.2d 170 (7th Cir. 1935).

B. Federal Food, Drug, and Cosmetic Act of 1938

In 1938, Congress augmented and stiffened the requirements for new drugs by providing for pre-market review to assess safety. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, ch. 675, § 505, 52 Stat. 1040, 1052. The act mandated that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug." *Ibid.* (codified as amended at 21 U.S.C. § 355(a) ["No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."]).

Congress inserted no pre-emption clause. Drug manufacturers remained subject to tort claims, independent of the new provisions for pre-market review and approval of new drugs. See, e.g., *Wennerholm v. Stanford Univ. Sch. of Med.*, 20 Cal.2d 713 (Cal. 1942); *Wechsler v. Hoffman-La Roche, Inc.*, 99 N.Y.S.2d 588 (N.Y. Sup. 1950); *Fielding v. Superior Ct. (Westwood Pharmaceutical Corp.)*, 111 Cal. App. 2d 490 (Cal. Ct. App. 1952); *E.I. DuPont de Nemours & Co. v. Ladner*, 221 Miss. 378 (Miss. 1954); *Arata v. Tonegato*, 152 Cal. App. 2d 837 (Cal. Ct. App. 1957); *Martin v. Bengue, Inc.*, 25 N.J. 359 (N.J. 1957); *Braun*

v. Roux Distributing Co., Inc., 312 S.W.2d 758 (Mo. 1958).

C. Drug Amendments of 1962

In 1962, Congress further amended the requirements for new drugs by providing that pre-market review assess effectiveness as well. Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781. When it did so, Congress expressly stated that "[n]othing in the amendments made by this Act [Drug Amendments of 1962] to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, § 202, 76 Stat., at 793; see also *id.*, § 104, 76 Stat. at 784 (amending section 505 of the Federal Food, Drug, and Cosmetic Act on pre-market review of new drugs).

In other words, nothing in the amendments invalidated the numerous provisions of state law enforced by the cases cited above, which clearly had already been valid in the absence of the amendments. There was no direct and positive conflict, and drug manufacturers remained subject to tort claims for failure to meet their duty of care and duty to warn state consumers. See, e.g., *Berry v. American Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1965); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Love v. Wolf*, 249 Cal. App. 2d 822 (Cal. Ct. App. 1967); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967);

Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689 (Cal. Ct. App. 1967); *Fritz v. Parke Davis & Co.*, 277 Minn. 210 (Minn. 1967); *Williams v. Vick Chemical Co.*, 279 F. Supp. 833 (S.D. Iowa 1967); *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623 (Mo. 1968); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2d Cir. 1969); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424 (Cal. Ct. App. 1969); *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Hornung v. Richardson-Merrill, Inc.*, 317 F. Supp. 183 (D. Mont. 1970); *Croft v. York*, 244 So.2d 161 (Fla. Ct. App. 1971); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288 (7th Cir. 1972); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51 (Cal. 1973); *Redfield v. Mead, Johnson & Co.*, 266 Or. 273 (Or. 1973); *Hoffman v. Sterling Drug, Inc.*, 374 F. Supp. 850 (M.D. Pa. 1974); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Crocker v. Winthrop Laboratories, Div. of Sterling Drug, Inc.*, 514 S.W.2d 429 (Tex. 1974); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375 (Or. 1974); *Whitley v. Cubberly*, 24 N.C. App. 204 (N.C. Ct. App. 1974); *Oresman v. G.D. Searle & Co.*, 388 F. Supp. 1175 (D.R.I. 1975); *Henry v. Richardson-Merrell, Inc.*, 508 F.2d 28 (3d Cir. 1975); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975).

D. Medical Device Amendments of 1976

When Congress enacted the Medical Device Amendments of 1976, it added the only other provision

on the effect of the Federal Food, Drug, and Cosmetic Act upon state and local law. Congress limited the scope of that provision to medical devices only:

> SEC. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (adding Section 521 to the Federal Food, Drug, and Cosmetic Act, codified as amended at 21 U.S.C. § 360k(a)).

Congress did not extend this pre-emption to the rest of the Federal Food, Drug, and Cosmetic Act in general and pre-market approval of new drugs in particular. See *Riegel*, 552 U.S., at ___, 128 S. Ct., at 1009 ("if, as the dissent believes, Congress wanted the two regimes to be alike[,] Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices."). The cases cited above on drug manufacturers' independent duties to

consumers were all on the books when Congress enacted the Medical Device Amendments of 1976. If Congress had wanted to end or restrict drug manufacturers' independent duty of care and duty to warn their consumers, and the history of tort relief for injuries caused by new drugs after the creation of pre-market review in 1938, then Congress would not have written a pre-emption clause limited to medical devices alone.

A recent decision by the Court further illustrates the point in juxtaposition.

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), concerned express pre-emption provisions in two federal laws on cigarette labeling and advertising. The Federal Cigarette Labeling and Advertising Act of 1965 specified the warning to be placed on a package of cigarettes. In a section entitled "Preemption," the act also provided that no other statement shall be required on any cigarette package, and that "[n]o [other] statement related to smoking and health shall be required in the advertising of [those] cigarettes." See Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92, §§ 4, 5, 79 Stat. 282, 283. The Court held that the first pre-emption provision, of 1965, "only pre-empted state and federal rulemaking bodies from mandating particular cautionary statements and did not pre-empt state-law damages actions." *Cipollone*, 505 U.S., at 519-520.

The act's successor, the Public Health Cigarette Smoking Act of 1969, strengthened the requisite warning's language, and provided instead that "[n]o

[other] requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of [those] cigarettes." See Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, § 2, 84 Stat. 87, 88 (amending sections 4 and 5). The Court held that the second pre-emption provision, of 1969, did pre-empt claims that state law required post-1969 advertising or promotions to "include[] additional, or more clearly stated, warnings." *Cipollone*, 505 U.S., at 524-525.[3]

Here, in contrast, Congress has inserted no such pre-emption provision, of either kind, regarding labeling approved under the Federal Food, Drug, and Cosmetic Act. Congress did not prohibit any other "requirement or prohibition . . . imposed under state law," as in the 1969 act. Congress did not prohibit any other statements in advertising, as in the 1965 act--which would not have pre-empted state damages actions in any case. Diane Levine proved that additional or more clearly stated warnings were required, and the Federal Food, Drug, and Cosmetic Act nowhere pre-empts the drug manufacturer's basic duties to its consumers under state law.

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[3] Similarly, *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005) held that a provision of the Federal Insecticide, Fungicide, and Rodenticide Act–that certain States "'shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter'"–pre-empted common-law actions. 544 U.S., at 443 (discussing 7 U.S.C. § 136v(b)).

III. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SETS MINIMUM STANDARDS FOR INTRODUCTION OF NEW DRUGS INTO INTERSTATE COMMERCE, AND STATE LAWS REQUIRING ADDITIONAL WARNINGS TO STATE CONSUMERS DO NOT CONFLICT WITH THE ACT.

Courts have frequently recognized that federal safety regulations between regulator and regulated entity set minimum standards, and that common-law tort claims could require stricter standards so long as they did not conflict with the federal regulatory scheme. E.g., *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 867-868 (2000) (recognizing that federal safety regulations set minimum standards and that common-law tort claims could require stricter standards so long as they did not conflict with the federal regulatory scheme).

Accordingly, most courts have held that the Federal Food, Drug, and Cosmetic Act's regulation of prescription drugs establishes minimum standards, for the introduction of new drugs into interstate commerce, and that a drug manufacturer's compliance with those minimum duties to the Food and Drug Administration does not pre-empt or repeal the drug manufacturer's separate duty of care and duty to warn its consumers, nor absolve the manufacturer of tort liability for failure to meet those independent duties. See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981) (rejecting argument that warnings were adequate if drafted by the Food and Drug Administration as required uniform labeling); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362

(4th Cir. 1975) ("In North Carolina, as elsewhere, compliance with federal laws and regulations concerning a drug, though pertinent, does not in itself absolve a manufacturer of liability."); *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1177 (5th Cir. 1988) ("FDA regulation does not generally preempt stricter state law standards for medical products."); *Hill v. Searle Laboratories*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability. [Citations omitted.] FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir.) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes."), cert. denied, 479 U.S. 950 (1986); *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085, 1096 (C.D. Cal. 2000) ("Several other courts have determined that FDA requirements are minimal standards and that FDA approval is not a shield to liability."); *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1033 (S.D. Ill. 2001) ("The reason why many courts find no preemption is that the FDA's drug labeling decisions impose only 'minimum' standards that are open to supplementation by state law through a jury's verdict enforcing a manufacturer's common law duty to warn."); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299 (D. Minn. 1988) ("widely held view that FDA regulation of prescription drugs establishes minimum standards, both as to design and warning"); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1030 (D.N.J. 1988) ("There is less sense of a comprehensive regulatory scheme, however,

than there is of labeling requirements which must be met at a minimum and certainly no suggestion that if additional requirements were imposed by the states any FDA regulatory scheme for IUD design and labeling would be destroyed. Courts have held with some consistency that while FDA regulation of prescription drugs may establish minimum standards for product design and warning labels, compliance does not necessarily absolve a manufacturer of tort liability"); *Feldman v. Lederle Laboratories*, 125 N.J. 117, 141 (N.J. 1991) (compliance with FDA regulations may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability), cert. denied, 505 U.S. 1219 (1992). But cf. *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 271-272 & n. 17 (3d Cir. 2008) (where the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires, holding that, "under the circumstances of this case, the plaintiffs' failure-to-warn claims are preempted by the FDA's actions taken in accordance with its statutory authority," and expressly not deciding "whether the FDA's mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger, [or] whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA's express rejection of a specific warning," and distinguishing the Supreme Court of Vermont's decision in *Wyeth* on these grounds).

Recognizing the drug manufacturer's independent duties to consumers to provide adequate warning at all

times after approval, the Food and Drug Administration's own regulations provide for immediate label changes without prior approval to provide adequate warnings:

> (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;
>
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
>
> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
>
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
>
> (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

21 C.F.R. § 314.70(c)(6)(iii)(A)-(E); accord *id.*, § 314.70(b)(2)(v)(A) (exempting labeling changes under § 314.70(c)(6)(iii) from the requirement of a supplemental application and approval prior to making the labeling change); *id.*, § 314.70(c)(4) (exempting labeling changes under § 314.70(c)(6) from the requirement to wait 30 days before making the change).

The regulation confirms that neither the Federal Food, Drug, and Cosmetic Act nor the implementing regulations preclude additional labeling in compliance with the drug manufacturer's duty of care and duty to warn. Again, the federal standards established between drug manufacturer and regulator are minimal standards for introducing the new drug into interstate commerce; they do not pre-empt the drug manufacturer's separate duties to consumers under state laws. With respect to labeling in particular, there is no conflict between drug manufactures' duties to consumers under state law and drug manufacturers' separate regulatory duties under the Federal Food, Drug, and Cosmetic Act.

The cases are legion where new drugs that the Food and Drug Administration has approved for introduction into interstate commerce–duties between drug manufacturers and the Food and Drug Administration having been met–subsequently cause great harm or death to individual consumers because the pharmaceutical company failed its separate duty of care and duty to warn the individual consumer. These cases demonstrate the importance of drug manufacturers' continuing and independent duties to consumers under state law.

One illustrative example concerns the drug DES. In the late 1940s, the Food and Drug Administration approved drug manufacturers' applications to sell diethylstilbestrol (DES) in interstate commerce. See, e.g., *Collins v. Eli Lilly Co.*, 116 Wis. 2d 166, 179 (Wis. 1984). Pharmaceutical companies marketed DES for use by pregnant women to prevent miscarriage. *Ibid*.

In 1952, the Food and Drug Administration decided that DES was no longer a "new drug," and drug manufacturers could sell it in interstate commerce without prior testing and new drug applications under 21 U.S.C. § 355(b). See *id.*, at 179; *Sindell v. Abott Laboratories*, 26 Cal. 3d 588, 593 (Cal. 1980). DES, however, caused growths and cancer in daughters of mothers who took DES during pregnancy, which did not manifest until after a minimum period of latency of 10 or 12 years. See, e.g., *Sindell*, 26 Cal. 3d, at 594. Medical studies questioned the therapeutic value of the promoted use to prevent miscarriage. E.g., *Collins*, 116 Wis. 2d, at 179, n. 6 (citing medical study published in 1953). In 1971, the Food and Drug Administration ordered drug manufacturers to cease selling DES for this use, and to warn physicians and the public that pregnant women should not use it. *Id.*, at 179.[4] Cases such as this illustrate the critical importance of a drug manufacturer's continuing and independent duties to consumers under state law, when post-market experience subsequently proves that the new drug should not be used as promoted and advertised.

CONCLUSION

Every day in this country, the ordinary consumer has no choice but to trust strangers to provide them with uncontaminated food, good medicine, honest financial services, safe cars, and the whole host of

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[4] The DES cases also revealed that drug manufacturers actually purchase insurance in anticipation of state tort actions. See, e.g., *Schering Corp. v. Home Ins. Co.*, 712 F.2d 4, 7-8 (2d Cir. 1983); *Eli Lilly & Co. v. Home Ins. Co.*, 653 F. Supp. 1, 3-5 (D.D.C. 1984).

other products and services associated with modern life. Every day, manufacturers' fundamental duty of care and duty to warn this ordinary consumer are critical consumer remedies and protections. With the Federal Food, Drug, and Cosmetic Act, Congress enacted minimum standards of safety and efficacy for sales of new drugs in interstate commerce, but it nowhere pre-empted the drug manufacturers' separate duty of care and duty to warn the individual consumer. Under the Federal Food, Drug, and Cosmetic Act, federal pre-market regulatory review and approval, and state common-law remedies and duties in the marketplace, exist in concert to secure a fair, just, and safe marketplace for all consumers.

For the reasons set forth above and in the Brief for Respondent, the judgment of the Supreme Court of Vermont should be affirmed.

Respectfully submitted,

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